THE INTERFACE BETWEEN TRADITIONAL KNOWLEDGE

AND

INTELLECTUAL PROPERTY

Traditional Knowledge And Intellectual Property: Options for Developing Countries

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PART 1: INTRODUCTION

Traditional Knowledge - Definition

Tradition in the expression 'traditional knowledge'(TK) does not mean old but refers to the manner of producing knowledge. Hence TK refers to knowledge that has been developed based on the traditions of a certain community or nations.[1] TK is one of the many existing systems of knowledge. The TK system constitutes a rich and diverse intellectual heritage. It is embedded in a wide array of cultures and sustains a broad spectrum of ways of life.[2] The knowledge and its contribution is dynamic and continuous.

Value of TK

1. Indigenous knowledge systems have helped to preserve and enhance biodiversity. Indigenous peoples nurture nature and its bounty especially as it provides them with the wherewithal for their very survival. Indigenous peoples and local communities have been developing seeds and food crops, using plants, animals, microbes and microorganisms to heal and clothe themselves. It is their innovation over millennia that has fed, clothed and healed the world. And these continue to do so.

   International acknowledgment

   The best international acknowledgement of this is the Convention on Biological Diversity (CBD). The CBD asks countries to

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[1] Weerawit Weeraworawit, 'International Legal Protection of Genetic Resources, TK and Folklore: challenges for the IP system', in *Trading in Knowledge,* Bellman, Dutfiled and Melendez-Ortiz (eds), Earthscan, 2003, p. 157 at p. 159.

[2] Nakashima D, 'TK: Resisting and adapting to globalisation' in as above, p. 131.

- Respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying life styles relevant for the conservation and sustainable use of biological diversity;

- Promote their wider application; and

- Encourage the sharing of benefits arising from its utilization.

Article 8(j)

- Protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation and sustainable use of biological resources.

Article 10 (c)

- Facilitate the exchange of information relating to indigenous and traditional knowledge.

Article 17(2)

- Encourage and develop methods of cooperation for the development and use of indigenous and traditional technologies.

Article 18(4)

2. TK value can also be seen from its immense economic contribution to modern industries –pharmaceuticals, botanical medicines, cosmetics and toiletries, agriculture and biological pesticides, amongst others.

The monetary estimation is made more difficult as often TK is often an essential component in the development of other products; and most TK-derived products never enter the market.

Agricultural crops

According to a study commissioned by the UN Development Programme, genes from the fields of developing countries for only 15 major crops contribute more than US$50,000 million in annual sales in the US alone.[3] Often the main beneficiaries are the countries and corporations of the North. The Rural Advancement Foundation International (RAFI), an international NGO, has estimated the value of farmer's varieties to both the food consumption and the agricultural earnings of developed countries. The International Maize and Wheat Centre (located in Mexico) contributes US$2,700 million in crop production in industrialised countries. For rice, from the International Rice research Institute, the contribution to the rice production of developed countries is estimated to be US$655 million per year. For beans the estimate is about US111 million from

[3] Conserving Indigenous Knowledge, An Independent Study by the Rural Advancement Foundation International, Commissioned by the UNDP, p.27.

material provided by the International Centre for Tropical Agriculture.[4] Industrial country agriculture also benefits enormously from the germplasm from potato, chickpea, barley, livestock breeds and many other materials from largely indigenous communities in developing countries. The global value added to rice yields by use of land races – traditional crop varieties – is estimated at US$400 million per year. (Dutfield - Unctad p. 144).

Pharmaceuticals

The same contribution obtains for pharmaceutical biodiversity. Three-quarters of plants that provide active ingredients for prescription drugs came to the attention of researchers because of their use in traditional medicine.[5] Among the 120 active compounds currently isolated from the higher plants and widely used in modern medicine today, 75% show a positive correlation between their modern therapeutic use and the traditional use of the plant from which they were derived. More than two thirds of the world's plant species – at least 35,000 of which are extimated to have medicinal value --come from developing countries. At least 7,000 medical compounds in the western pharmacopeia are derived from plants. According to one estimate, the annual value of developing country germplasm to the pharmaceutical industry was as high as US$47,000 million as at 2000.[6] RAFI estimates that US$32 billion of sales of pharmaceuticals world-wide are based on traditional medicines. Yet the developing countries' exports were only US$551 million – an incredible shortfall. The importance of medicinal plants is highlighted by the work of the US National Cancer Institute. Between 1986 and 1992, it paid for the collection of 23,000 plant samples of 7,000 species, almost all of which came from the countries of the South.

Soil bacteria

The contribution of indigenous peoples to world health comes also from medicines derived from the soils. Several leading pharmaceutical multinationals - Merck, Pfizer, Bristol Myers - are busy collecting micro-organisms from the soil from the developing world. Indigenous peoples have long known and valued the properties of certain soils. They may not be aware of the exact bacteria or fungi resident in the soil, but they know of the anti-tumor, antibiotic or steroid characteristics of certain soils.

At least 12 % and 4% of the bacterial accessions in the American Type Culture Collection are derived form developing countries, mostly from soil samples. In 1990, for example, the University of Florida patented a Brazilian fungus known

[4] ibid. pp. 27-28.
[5] Kloppenburg, J. Jr., 'No Hunting! Biodiversity, Indigenous Rights, and Scientific Poaching', Cultural Survival Quarterly, summer 1991, p. 15
[6] see UNDP report, fn 2, at p. 30.

to be lethal to fire ants that can cause more than a billion dollars in damage to US crops. Brazilian farmers were aware that something in the soil kills fire ants.

3. Its value in enhancing and integrating indigenous and local communities by its cultural and spiritual values. This is of course, not measurable in economic terms.

PART 2: THE START OF THE MARGINALIZATION OF TK - THE EMERGENCE OF OWNERSHIP RIGHTS IN RESOURCES AND ASSOCIATED TK

An open system: common heritage of mankind

Traditionally, genetic resources have been considered as the common heritage of mankind. They were freely accessible to all. This was publicly proclaimed – in relation to plant genetic resources – by the International Undertaking on Plant Genetic Resources - a non-binding agreement concluded under the auspices of the UN Food and Agriculture Organisation (FAO). Plant genetic resources were in the global commons and no country had the exclusive right to prevent others from accessing and using them. There was also no concept of sovereign rights in genetic resources.

Then it all started ...

What contributed to the emergence of property rights for commercial benefits in this area was the enactment in the early 1960s of an international convention – the Union for the Protection of New Plant varieties (UPOV – following the acronym from its French name). The South, where the biodiversity was concentrated, was tapped freely for source material - farmers' germplasm. Corporate interests – almost entirely from the North – invaded the local commons of the South for free, made 'improvements' in the breeding process by modifying the plant variety's characteristics and quality, and claimed property rights. The innovative contribution and knowledge of local communities to the evolution of seeds and genetic resources were ignored and remained unrewarded. This inequitable exploitation on the basis that the resources were 'the common heritage of mankind' could not continue unabated. It spawned a debate in the FAO in the 1970s. The Undertaking was adopted in 1983. The debates finally led to the recognition of both Plant Breeders' and Farmers' Rights in 1989.[7] An international gene fund was set up to finance the conservation and utilization efforts of farmers. But this fund remained inoperative as there were no contributions by the corporations and the countries of the North.

On 3 November 2001 under the auspices of the FAO a binding agreement was adopted – the International Treaty on Plant Genetic Resources for Food and Agriculture. It incorporates farmers' rights and a mutilateral system for access and benefit sharing – of which more will be discussed later.

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[7] See further: Gurdial Singh Nijar, *In Defence of Local Community Knowledge and Biodiversity,* TWN, Paper 1, 1996, pp.6-9.

Patent rights and biotechnology

The inequity was further extended by the extension of patent rights to living organisms and later to genetic material – by article 27.3 (b) of WTO/TRIPS. Even of greater impact were patents in relation to discoveries especially in the biotechnology field. The 'products of nature' doctrine was circumvented by allowing for the patenting of isolated, purified, and identified gene sequences. The holder of a patent on such gene could prevent others downstream from making or using that gene. The IPRs recognized included, as well, products based on or derived from TK.

PART 3: THE CONCEPTUAL 'BASIS' FOR THE IMPAIRMENT

1. Differing world view of reality

There is a fundamental differing world view of reality between the traditional and the scientific. Scientists adjudge only that which is verifiable by their criteria as reflecting reality. The rest – like TK – is considered unscientific, not rational and therefore incapable of reflecting and understanding reality. In other words, science is deemed a superior knowledge system to TK. Given the institutional power of science in mainstream society, it adjudges other knowledge systems.

2. The usurpation of TK through IPRs?

This conceptual bias was then universalized through internationally binding trade agreements - mainly as established by the WTO/TRIPS agreement. The definitional constructs for obtaining patents and other intellectual rights recognises and rewards the creativity of individuals not communities; one-off 'inventions' as against inter-generational community innovations; and inventions made for the market place as distinct from those for the social good. In other words the scheme appears inherently incompatible with according protection and recognition of the innovations at the heart of TK knowledge systems. This has resulted in the usurpation of TK and the failure to provide fair and equitable compensation to the creators and holders of this knowledge.

3. The marginalization of TK

The result is that resources are acquired by industry – directly or indirectly from the TK knowledge systems – and monopolistic ownership claims are made over these. This leads in the long term to the marginalisation of the knowledge system itself. For only the creativity of the industry is rewarded in the general scheme of patent law. Even if communities could afford to do so, it is clear that industry is in an advantageous position compared to communities to claim a patent. Communities may know of the useful trait and use of a plant or animal. But patents are given to those who can describe the phenomenon in the language of chemistry or molecular biology and patent law. A

company may not get that patent by simply describing the mode of action or the active compound – but it could claim a patent for the synthetic version of the compound or even a purified extract. (Dutfield – p. 145).

4. The fragmentation and atomization of the cultural system.

Additionally industry acquires select elements of the resource in isolation from the larger cultural context of indigenous and local communities. This encourages fragmentation and atomization of the cultural system. For example, dissension and social discord is triggered when those from amongst the community are designated 'owners' of a community knowledge resource.

5. The intervention of the market place.

Also, local knowledge is delivered - through conventional IPRs - to the global market place in which communities are ill-suited to participate.

PART 4: THE RESULT: INEQUITY, BIOPIRACY, MARGINALSIATION OF TK

Western companies often synthesize derivatives of plant mixtures used and identified by indigenous peoples by modifying the molecular structure of one of its active ingredients.[8] Everyone involved in the process benefits enormously. Except, of course, those indigenous peoples who developed the product in the first place! Such usurpation of the knowledge of indigenous peoples - referred to as 'biopiracy' – continues unabated post-CBD. The examples of biopiracy are too numerous to recount. From the neem plant of India to the devil's claw of Southern Africa, to the sacred sangraderago of South America. Pharmaceutical companies are the main beneficiaries of this biopiracy.

Some examples: the root of the serpent-wood species *rauvolfia serpentina*, widely used for centuries in India for a number of maladies including hypertension, is a classic example of the commercialisation of indigenous knowledge. By 1967, almost 90% of the anti-hypertensive drug market in the US was based on these roots, and the tree continues to be the basis of several other important medicines.[9] Companies from the US and Japan have been granted some 34 patents for various uses and processes relating to the neem tree. Yet Indian traditional knowledge of the use of the neem dates back 5,000 years. It is part of their Ayurved knowledge system. The US National Research Council recently noted that the people of India treasure the neem tree as a local pharmacopeia:

> 'For centuries, millions have cleaned their teeth with neem twigs, smeared skin disorders with neem-leaf juice, taken neem tea as tonic, and placed neem leaves in their beds, books, grain bins, cupboards, and closets to keep away troublesome bugs.

[8] See the example of the *curare,* later in the text.

[9] Axt, supra, p.7.

> The tree has relieved so many different pains, fevers, infections, and other complaints that it has been called the 'village pharmacy'. To those millions in India neem has miraculous powers, and now scientists around the world are beginning to think they may be right.'[10]

While acknowledging and drawing upon the knowledge systems of indigenous peoples and profiting hugely as a result, the knowledge itself is deprecated as being primitive.

PART 5: RESTORING THE BALANCE

1. Integration of TK into scientific frameworks?

Could the integration of two knowledge systems – the traditional and the scientific be the solution to maintaining the viability of TK? After all, science recognizes TK as a valuable resource in their research and especially in cutting lead time for the final development and creation of a product. However integration has led, or could lead, to the extraction of relevant knowledge through a process of scientific validation – ostensibly to separate the 'useful' from the 'useless', the objective from the subjective, knowledge from belief. This may be good for science – but it could result again to the dismemberment and fragmentation of TK systems and the acceleration of the demise of the TK system and its replacement with the scientific system. (Nakshima 132/3).

2. Acknowledging the co-existence of the two knowledge systems

There needs to be recognition that TK and the scientific knowledge system are plural and differing systems that conceive the world in completely different ways. The TK world is a place with pathways between the natural and societal realms - where spirituality infuses everyday objects and everyday acts. (Naka 133) More importantly, there is no objective basis for suggesting that one view is superior to the other. The 'pre-eminence' is as a result of a societal choice – by a self assertion of the predominant – and is not defensible from any neutral or acultural perspective.

How, for example, can scientists possibly suggest that indigenous peoples stumbled by pure chance as to the properties of the *curare* plant. Several millenia ago, the Amazonian hunters developed this muscle-paralyzing substance as a blow-gun poison. It kills tree-borne animals without poisoning the meat while causing them to relax their grip and fall to the ground. Monkeys hit with an untreated arrow wrap their tails around branches and die out of the hunter's reach. Modern medicine realized the vast potential of the *curare* in surgery. For it interrupts nerve impulses and relaxes all muscle including breathing muscles. There are forty types of *curares* in the Amazon made from seventy plant species. The kind used in modern medicine comes from the Western Amazon. It is produced by combining several plants and boiling them for seventy-two hours. The

[10] see further, Nijar, *TRIPS and Biodiversity: The Threat and Responses*, 1996, Third World Network, Paper 2, pp. 14-15.

mortal fragrant vapors emitted by the boiling have to be avoided. The final product is a paste that is inactive unless injected under the skin. If swallowed, it has no effect. As Narby notes:

> *'When one asks these people about the invention of curare, they almost invariably answer that it has mythical origin. The Tukano of the Colombian Amazon say the creator of the universe invented curare and gave it to them.'*[11]

Western 'science' may attribute the manner of the acquisition of the knowledge to pure chance and accidental 'stumbling upon' a result; or at its most charitable, the result of cumulative years of this happening. But traditional cultures have quite different explanations. The *Quirishari* living in the Amazon, for example, say they know that a plant cures the potentially mortal bite of the *jergon* snake from the pair of white hooks resembling snake fangs embossed on the plant. *'We know this thanks to these hooks, because that is the sign nature gives.'*[12] Indeed ethnobotanists no longer dismiss the possibility that there is a communion between nature and indigenous peoples that yields this vast information. The foremost ethnobotanist of the 20th century, Richard Evans Schultes, writes about the healers of a region in Colombia that he considers as one of the centres of Western Amazonian shamanism

> *'The medicine men of the Kamsa and Inga tribes of the Valley of Sibundoy have an unusually extensive knowledge of medicinal and toxic plants ... One of the most renowned is Salvador Chindoy, who insists that his knowledge of the medicinal value of plants has been taught to him by the plants themselves through the hallucinations he has experienced in his long lifetime as a medicine man.'*[13]

Our bias, or worst, ignorance, should not be the basis of a hierarchy of recognition; both knowledge systems should be equally regarded. TK is not just random bits of information but integral components of dynamic societies and cultures.

PART 6: LOOKING AT AREAS TO ASSIST RESTORATION OF THE BALANCE: OPTIONS FOR DEVELOPING COUNTRIES - AT THE INTERNATIONAL AND THE NATIONAL LEVELS

There has been a momentum by developing countries in various international fora for proactive measures to prevent the misappropriation of genetic resources and associated TK - spurred on by the CBD provisions relating to TK. There have been numerous proposals. These range from the creation of new forms of stand alone forms of protection of community intellectual knowledge to the simple option of simply preventing any

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[11] See footnote 3, at pp. 39-40.

[12] Quoted in Jeremey Narby, *The Cosmic Serpent, DNA and the Origins of Knowledge'*, Phoenix 1999, p. 29.

[13] Schultes and Raffauf, *The Healing Forest: Medicinal and Toxic Plants of the Northwest Amazonia*, Dioscorides Press, 1990, quoted in Narby, ibid, at p. 41.

forms of IPRs over such knowledge. Some of the efforts of developing countries are explored – both at the international and national level.

A. THE INTERNATIONAL FRAMEWORK

I. IN THE CONTEXT OF WTO/TRIPS

The proposals of developing countries at the WTO TRIPS Council

Under the CBD, the country of origin regulates access rights and is entitled to the benefits. 'Country of origin' is defined as the country which possesses those genetic resources in in-situ conditions, that is, within ecosystems and habitats. In the case of domesticated and cultivated species, where the genetic resources have developed their distinctive properties.[14] 'Habitat' is defined as the place or type of site where an organism or population naturally occurs.[15]

Developing countries at the WTO are seeking to require disclosure of the country of origin of the material and associated TK in patent applications as a mechanism to prevent its unauthorized use and ensure the sharing of benefits.[16] They wish to make the WTO provisions compatible with the CBD provisions relating to access and benefit sharing of genetic resources and associated TK. They argue that this could effectively prevent their misappropriation.

The proposals of developing countries at the WTO TRIPS Council

After a long gestation period and much rancorous debate, nine developing countries[17] the proposal was formally submitted[18] on 31 May 2006.

The proposal seeks to amend the TRIPS Agreement – in particular Articles 27.3 and 29[19] - to require, as a condition for patent grant:

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[14] Article 2 – defining 'country of origin' and 'in-situ conditions',

[15] Article 2 CBD.

[16] These definitions give rise to a whole host of problems. This is made more so when genetic sequences usually appear in more than one country. Where can a gene be said to have developed its distinctive properties? Where did the gene naturally occur? Tension is likely to develop over these uncertainties – especially amongst developing countries seeking to capture the benefits of allowing access and use of its genetic material. Rubber and palm oil in Malaysia, for example, were brought from Brazil and Africa respectively during colonial rule. Over the years these resources have been developed, and can be said to have acquired, distinctive properties. But is the distinctiveness unique enough and, more importantly, is this fact accepted by those countries from where the resource was first taken?

[17] Brazil, India, China Pakistan, Peru, Thailand and Tanzania. A revised version adds China and Cuba as cosponsors.

[18] WT/GC/W/564.

a. the disclosure of the source and country of origin of the genetic resources including TK used in the invention;
b. evidence that the country of origin had consented to its extraction and use;
c. evidence of fair and equitable sharing of benefits under the national regime.

The international framework of protection envisaged would have as key features a mandatory certification from the country of origin when applying for a patent – a certificate of origin – ensuring these three aspects.

The rationale offered: need for international framework to supplement national regimes

This, say the developing countries, is imperative to implement TRIPS and the CBD in a mutually supportive way. In particular, these proposals would be a vital supplementary measure to national regimes and a necessary incentive for patent applicants to comply with the prevalent laws and practices of the countries of origin of the genetic resources including TK, in accordance with the objectives and norms of the CBD. More importantly, they argue that the proposals highlight the fact that bio-piracy is a global problem mostly involving the acquisition of material and TK in one country and the seeking of a patent over that material or inventions deriving from that material and TK, in another country. National regimes would not be sufficient to protect and fully preserve biological materials and associated TK, given the transnational facet of the problem. The problem was that any effort by national patent offices and other national authorities to prevent bio-piracy, as well as to enforce prior informed consent and benefit sharing mechanisms, does not automatically lead to similar actions in respect of patent applications in other countries.

A paper commissioned by the Secretariat of the CBD states that the CBD places the responsibility of ABS on both the user and the source provider. Yet each country's national legislation – both in developed and developing countries – emphasise almost exclusively on access to the genetic resources of that country. The paper notes that little relevant user laws have been adopted:

> *'At present, developed country legislation does not appear to address the separate requirement of the adoption of legislation or other measures with the aim of sharing in a fair and equitable way ... the benefits arising from the commercial and other utilization of genetic resources as required in Article 15.7'. It is certainly perceived not to support any attempt to enforce ABS requirements of source countries. Claimants seeking remedies or enforcement of ABS principles in these countries, would be forced to use basic provisions of contract and property*

[19] The TRIPS Agreement is understood as permitting members to introduce obligation to disclose the origin of genetic resources and TK in patent applications. This proposal obliges members to introduce mandatory obligation. Hence the need for an amendment.

law, which evolved centuries before any concept of genetic resources as property, and which do not provide any legal basis for ABS actions'.[20]

A brief background to the emergence of these proposals

In the Uruguay Round negotiations that led finally to the WTO, the relationship of trade and biodiversity – the WTO and the CBD, and in particular the protection of the innovations of indigenous and local communities - was not discussed at all.[21] Discussions on the relationship began in 1995 in the WTO in the Committee on Trade and Environment. Developing countries introduced these discussions in the TRIPS Council – that is the institutional body in charge of TRIPS – when Article 27.3(b) came up for review in 1999. By the time of the Seattle WTO Ministerial meeting, developing countries had proposals to amend TRIPS to include TK. There was no outcome on this issue but clearly the momentum was gaining pace and discussions continued through 2000 – 2001 about the relationship between the CBD and TRIPS. The breakthrough came at the Doha Ministerial. The Ministerial Declaration at this meeting instructed the TRIPS Council to examine, among other things, the relationship between TRIPS and the CBD and the protection of TK and folklore. Paragraph 12 identified it as an outstanding implementation issue. This was then discussed at the TRIPS Council and is now part of the outstanding issues at the Trade Negotiations Committee (TNC) level. The declaration of the December 2005 Hong Kong Ministerial requested the WTO director general to "intensify his consultative process" and report to the Trade Negotiations Committee and the General Council, which will consider progress and "take any appropriate action" by the end of July.

Three broad approaches

At these discussions, 3 broad positions have emerged. The first, says there is an inherent conflict. Hence the need to reconcile the 2 treaties as part of the review process of Article 27.3(b). The second, is that there is no legal conflict at all. The third is that both these treaties should be read in a mutually supportive way. On this view, there is no need to do anything at the national or international level. However a group of developing countries feel that to avoid the potential for conflict, there is need to amend TRIPS. The proposals for amendment by the 9 countries are in support of this position.

Elaboration of the proposals:

Fair and equitable sharing enhance credibility of patent system

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[20] UNEP/CBD/WG-ABS/4/INF/6, IUCN-Canada, *Analysis of Claims of 'Unauthorised Access and Misappropriation of Genetic Resources and Associated TK'* IUCN-Canada, 2005, at p. 28.

[21] *'The question of new forms of protection adapted to the particular circumstance of indigenous peoples/communities was not raised during the TRIPS negotiations'*, comments by The Committee on Trade and Environment, : WT/CTE/W/8.

The proposers suggest that providing evidence of fair and equitable benefit sharing arrangements arising out of the utilisation of the genetic resources[22] and TK in the invention with the source and country of origin and/or local/indigenous community is fair and would enhance the patent system's credibility.

The following factors are suggested to determine whether there is equitable and fair benefit sharing. First, the sharing of benefits is premised upon mutually agreed terms – MAT - in the context of Article 15(7) of the CBD, covering elements relating to the conditions, obligations, procedures, types, timing, distribution and mechanisms of the benefits shared. Secondly, there is a reporting obligation on issues relating to patenting or commercialisation especially where future benefit sharing is contemplated.

Where no national regime on ABS

Where there is no national regime, the patent applicant must declare that there was no national access and benefit sharing regime in the country of origin, but that there was, in any case, benefit sharing or an arrangement for future benefit sharing with the authority or community in charge of the location where the genetic resources and TK were accessed, in a manner that fully respects the prevalent laws, regulations and practices of the country of origin.

Effect where no benefit sharing

Where genetic resources and TK were used in an invention but no evidence of benefit-sharing or an arrangement for future benefit sharing has been furnished as required before the examination or grant of a patent, the legal effect could be that the application would not be processed any further until the submission of the necessary declaration and evidence.

Sanctions and penalties

This could be accompanied with penalties, including criminal penalties, and time-limits within which the proper declaration and evidence must be provided. Otherwise the application could be deemed withdrawn. The failure to provide evidence of benefit sharing should justify the non-processing of the application.

Where the failure to provide evidence of benefit sharing is discovered after the grant of a patent, the legal effect could include:

- Revocation of the patent where it is determined that there is fraudulent intention behind the failure to provide evidence of benefit sharing. Additionally or alternatively, criminal and/or administrative sanctions may also be imposed, particularly to ensure adequate compensation where it is eventually determined that no benefits were shared or are intended to be shared;

[22] This term would include derivatives. See later text at p.

- Full or partial transfer of the rights to the invention, also as an alternative to revocation.
- Criminal and/or civil sanctions, outside the patent system, including the possibility of punitive damages, where it is determined that the patent holder in fact provided benefits but did not provide the evidence in the application.

Responses from the developed countries

So far the response to the proposals from the developed countries has been mixed. The US, in particular, sees no conflict between the CBD and TRIPS, and argues that CBD obligations can be satisfied by taking action at the national level, without the need for action to be taken on the patent system or at the WTO. Essentially, the US argues that these requirements are extraneous to the criteria for establishing the grant or refusal for a patent – namely, that the patent is new, involves an inventive step and has industrial utility. The European Union's position is that it could agree with the proposals of the developing countries as a basis for discussion; however it does not agree with the proposals requiring disclosure of evidence of prior informed consent and benefit sharing. It is also against any form of penalties under patent law.

A large number of countries support the continued discussion on disclosure, and are agreeable to the suggestion that the future meeting discuss the form and content of the proposals.[23]

The text-based amendment presented by developing countries on 6th June 2006

On 6th June 2006 the developing countries presented actual text. They suggest that countries are now ready to begin text-based negotiations, without committing them beforehand to agree to the amendment of TRIPS in the end.

The text-proposal is to create a five-paragraph Article 29bis in the TRIPS agreement establishing requirements for the disclosure of origin of biological resources and traditional knowledge. Article 29 relates to conditions on patent applications, including disclosure of the invention details. The proposal would require greater detail in the disclosure of the country providing the resources as well as the country of origin "after reasonable inquiry." It also would require evidence of compliance with legal requirements in the providing country for prior informed consent to access the resources, and fair and equitable benefit-sharing of commercial uses. Other measures include required updates and enforcement.

[23] The Report of the last TRIPS Council of the WTO agreed that the 'work (on the relationship between the TRIPS and the CBD) continue on the basis of para 19 of the 2001 DOHA Ministerial Declaration and the progress made in the Council for TRIPS todate': S. Shashikant, TRIPS transition period for LDCs extended by 7.5 years with conditions, Third World Economics, TWN, issue 368, 1-15 Jan 2006, 21 at 22.

The developed country opponents – mainly Australia, Canada, Europe and the United States - say there is nothing new in the presentation and continue to hold the view that it is premature to consider an amendment to TRIPS to address concerns about misappropriation of genetic resources and traditional knowledge; or they argue that the proposed amendment is too broad.

Many more developing countries are considering supporting the proposals.[24] Colombia, Ecuador, and Venezuela are discussing the amendment matter in their capitals, with at least Colombia indicating it may sign on. Argentina, cited as an opponent, has softened its position to say it is under discussion in the capital as well. There are also other countries considering signing on.

However, the Philippines, Singapore and Taiwan have raised concerns. Singapore is reported to have said that an approach to preventing misappropriation through contracts has been effective, but did not provide examples. The Philippines raised technical questions but indicated support for the objective.

Norway, which has stated support for discussing the matter at the WTO, said it would produce its own proposal, possibly watering down provisions on prior informed consent and benefit sharing, according to a source. The European Union, speaking for 25 countries, cited its proposal at the World Intellectual Property Organization and said it will be a "challenge" to reconcile the two. However, the EU and Switzerland appear not be opposed to discussing the matter at the WTO, and Brazil explicitly stated that the WTO is the proper venue, the source said.

Switzerland prefers disclosure through WIPO's Patent Cooperation Treaty.[25]

The outcome of negotiations, should they occur - according to IP Watch quoting as developing country source - could be somewhere between the proposed WTO amendment and the EU's WIPO proposal. The EU proposal differs from the WTO proposal in at least two key ways. First, it would limit the focus to disclosure of origin of genetic material directly used in the invention. The proposed WTO amendment would require disclosure of origin whether directly or indirectly used in the invention, and would extend to traditional knowledge as well.

In addition, the European Union views some terms in the WTO amendment proposal as too broad. The EU proposal would use the term 'genetic resources'. It views the developing countries term 'biological resources' as too broad. And the European Union is concerned about the burden put on patent applicants by use of the term 'reasonable' in determining their requirements for proper disclosure.

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[24] Report by IP Watch: *http:// ip-watch.org/weblog/wp-trackback.php?p=326.*

[25] At the 6 June meeting, Switzerland said its priority is for the extension of elevated GI status to other products beyond wines and spirits.

Japan, Korea and the United States continue to argue that there is no actual mandate to negotiate on this issue. In the 6 June meeting, the United States was challenged to put forward the precise legal reason for this, but apparently failed to do so.

The CBD issues are indirectly tied to the GIs talks, as the proponents of each have shown willingness to possibly support the others' proposal in exchange for support of their own, sources said. Under this theory, Australia's opposition to CBDs could be explained by its staunch opposition to GIs, one source said.

Informal special session on 14 June 2006

At a special session of the TRIPS Council on 14 June, Japan and Norway tabled their proposals. The position now is that while there are a number of proposals, there is no common text that could be the basis for future negotiations.[26]

Norwegian proposal

The Norwegian proposal – no different from its earlier one - supports the idea of amending the TRIPS agreement to make disclosure of origin and the source of genetic resources and traditional knowledge mandatory in patent applications, but differs when it comes to sanctions. Patents would not be revoked if incorrect or incomplete information has been given in the patent applications, which is identified after the patent is granted. The Norwegian proposal says this should be penalised outside the patent system.

It calls for mandatory disclosure only of the country of origin, not of prior informed consent and benefit sharing. Only if the national law requires prior informed consent from the provider, should this requirement be met as well. Norwegian law requires disclosure of origin and prior informed consent in its national law.

At the last WIPO IGC meeting Norway tabled a complementary proposal on traditional knowledge.[27] It requires that the source and origin of traditional knowledge also be disclosed in patent applications although it is not linked to genetic resources.[28]

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[26] There are several contentious areas that have been raised. Examples include: Is there a need to disclose more than source (asked by Switzerland? Why is the term "biological" resource used instead of "genetic" resource (EU and the Philippines)? What is to be understood by the term "associated traditional knowledge" (EU)? Will the requirement to publish require publication with the patent or separately from the patent application (EU)? The sponsors of the amendment have answered these questions.

[27] IP Watch, WIPO, 25 April 2006.

[28] On this point, and some other areas, it differs from the EU's proposal at WIPO although it is similar.

II. WORLD INTELLECTUAL PROPERTY ORGANISATION - WIPO

In 2004 Brazil introduced the development agenda at WIPO. This includes proposals for the protection of traditional knowledge, traditional cultural expressions (folklore) and genetic resources. These negotiations ended in a stalemate at the last meeting of the intergovernmental committee held in June this year – 2006 - over whether to address substantive legal text before completing work on objectives and principles.

At the heart of this debate is the desire of Brazil, South Africa (on behalf of Africa), India and others to include issues including on TK as part of the whole negotiation so that it might lead to a legally binding instrument for the protection of these areas. But Japan, the United States and others are against their inclusion before the completion of talks about principles and objectives which they say would represent a foundation for further discussions.

The substantive provisions deal, among other matters, with protection against misappropriation, the legal form of the protection and fair and equitable benefit-sharing and recognition of knowledge holders and prior informed consent.

The position of the industrialized countries and their bioindustry is that the enforcement of ABS should be separate from the administration of patent rights; that contracts between countries made on mutually agreed terms and not an internationally binding instrument should resolve the problem; and that there should be developed a universal system to harmonise existing TK databases and digital libraries.[29]

The committee will meet again on 4-12 December 2006, at the halfway point of its two-year mandate.[30]

III. THE CONVENTION ON BIOLOGICAL DIVERSITY

The Convention on Biological Diversity (CBD) provides an international recognition of the ownership rights of countries over their genetic resources. This was important for the South which holds most of the biological resources and diversity of the world. A key feature of the CBD is Article 16(5) which establishes that Parties will cooperate to make sure that any intellectual property rights do not run counter to the objectives of the CBD –

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[29] See for example, 'Comments of the American Bioindustry Alliance on WIPO Paper WIPO/GRTK/IC/9/5, 'The Protection of TK: Revised Objectives and Principles', July 31 2006. The ABIA was established by the American biotechnology companies to voice their positions at, among others, international fora – WTO, CBD and WIPO. Its members include: Pfizer, Merck, Bristol Myers Squibb, General Electric, Eli Lilley and other leading biotech and pharmaceutical industry players.

[30] The debate focused largely on 2 documents: WIPO/GRTKF/IC/9/4; and WIPO/GRTKF/IC/9/5.

the conservation and sustainable use of biodiversity and its components and the fair and equitable sharing of the benefits from the utilization of genetic resources.

Establishing an International Regime on Access and Benefit Sharing (ABS)

The 7th meeting of the Conference of the Parties in Kuala Lumpur in 2004 – COP7 - set in motion negotiations for an International Regime (IR) on access and benefit sharing of genetic resources. It established a working group and provided the terms of reference. The scope of the potential IR includes TK, innovations and practices in accordance with Article 8(j) of the CBD. Among the elements in the terms of reference are: measures to ensure with the prior informed consent of indigenous and local communities holdoinf TK associated with genetic resources; internationally recognized certificates of origin/source/legal provenance of genetic resources and associated TK; disclosure of origin/source/legal provenance of these in applications for IPRs, and the recognition and protection of the rights of indigenous and local communities over their TK associated to genetic resources 'subject to national legislation'.

The working group, after 2 meetings, has produced a heavily bracketed text in Granada in 2005 representing a range of often diametrically opposing views on many key facets.

COP8 held in Brazil in March 2006, agreed to continue negotiations on the IR on the primary basis of the Granada text. The next round of negotiations is expected to be held in mid-2007. A clear schedule of work has been set. It was also agreed that the negotiations be concluded 'as soon as possible and in any event no later than COP 10 scheduled for 2010'.

The decision highlights, as a possible measure for the development of the international regime, the disclosure of origin/source/legal provenance of genetic resources in IPR applications in national jurisdictions – in accordance with Art 16(5) of the CBD.

A group of technical experts will be appointed and they will prepare a report on the form, intent and functioning of an internationally recognized certificate of origin/source/legal provenance. In particular the group is to look at its usefulness in fulfilling the objectives of the CBD, in particular Articles 15 and 8(j). The issue of the desirability of this certificate is left open. The group is expected to meet early next year – 2007.

COP 8 also dealt with national measures that countries can take to support compliance with the prior informed consent (pic) and mutually agreed terms (mat) provisions of Article 15 of the CBD. It urges Parties and others to continue taking such measures as will support compliance with pic and mat –where there is utilization of genetic resources or associated traditional knowledge – in accordance with Article 15 of the CBD and national legislation.

Developing countries are firm that derivatives are not excluded from the scope of the decision. They consider the expression in the decision - *utilization of genetic resources* and associated traditional knowledge - to include the use of derivatives from genetic resources. Utilization of genetic resources in the context of the CBD means the use of **any** larger or smaller part, extract or chemical compound from plant, animal, microbial or other origin **containing** genes. The CBD in Article 2 does not define genetic resources on the basis of its reproductive functions but on the basis of its composition. Thus, the aims pursued with such an utilization are not restricted to the reproductive capabilities of a genetic resource, example: propagation or using isolated genes, but to all kinds of use. Thus, utilization of genetic resources would include activities like the production of cosmetics based on the use of plant material, drug development based on the use of marine microorganisms, or, of course, using isolated genes in modern biotechnology.

In any event, it is for a country to define by its national legislation what use of genetic resources is to be disclosed in the certificate. It is for a country then to require the disclosure of pic and mat in relation to derivatives.

Cooperation with the Working Group (WG) on article 8(j)

The Article 8(j) WG have expressed a clear call for the ABS WG developing the International Regime (IR) to work in tandem with them on all matters relating to TK. It has asked for the mandate to elaborate specific elements and measures relevant to the protection of TK associated to genetic resources in the IR. It has also asked for the creation of an advisory group – consisting of indigenous peoples and local communities - to undertake a review of the negotiations of IR and to provide expert advice to both the Working Groups on matters relating to the protection of GR-TK.[31] This request has not been acceded to by COP8. It has decided nonetheless to allow for full and effective participation of indigenous peoples and local communities in all matters relating to TK in the development of the IR within the rules of procedure. Specifically, they request them to provide their views so that these can be compiled and made available to the ABS WG and invites chairpersons to 'facilitate the effective participation of their representatives' and to 'consult them, as appropriate, on issues related to TK, innovations and practices and associated genetic resources, ... in accordance with the rules of procedure'.[32]

IV. UN CONFERENCE ON TRADE AND DEVELOPMENT - UNCTAD

The 2004 COP7 invited UNCTAD to analyse issues relating to the implementation of disclosure of origin requirements in the IPR system. Its principal finding was that there was a need for an international system of mandatory disclosure of origin requirements to prevent misappropriation of genetic resources and associated TK, to promote compliance

[31] Presentation to COP8 by the International Indigenous Forum on Biodiversity, Brazil, March 2006.

[32] Decision VIII/5, UNEP/CBD/COP/8/31, p. 67. The Rules of Procedure allow non-Parties to participate in any meeting as observers upon invitation of the President 'unless at least one third of the Parties present at the meeting object'. In any event observers have no right to vote: rules 6 and 7.

with the CBD access and benefit sharing provisions, and to prevent misuse of the IPR system. The report noted that because not all countries had laws imposing these disclosure requirements, there was a need for a new international treaty provisions to assure worldwide implementation of such disclosure requirements.[33] It recommended that these provisions be included in the WTO because of its broad membership and dispute settlement procedures.[34] It was of the view that although the disclosure requirements were compatible with WIPO-administered treaties, those treaties ' ...were not adopted with disclosure of origin requirements in mind'. In so far as they may be incompatible then those WIPO treaties had to be amended.[35] The Report also recommended the need for addressing a number of issues in the PCT regime. These included revising rules and adopting new procedures.[36]

V. THE INTERNATIONAL TREATY ON PLANT GENETIC RESOURCES – FAO

The treaty, negotiated and concluded under the UN Food and Agricultural Organisation (FAO), deals with plant genetic resources for food and agriculture (PGRFA).[37] It establishes a specific mode of establishing access and benefit sharing in respect of particular categories of genetic resources – those for food and agriculture. The treaty establishes access and benefit sharing for a list of 35 crops and crop complexes and 29 forage species.[38] This list can be expanded by consensus of the government parties to the FAO. Non listed genetic resources can also be the subject of mutual access and benefit sharing modeled on the treaty.

These crops have crossed boundaries since 100s of years ago. The whole world is interdependent upon them.[39] They have been developed by indigenous and local communities of farmers – primarily in developing countries. Many germplasms of the popular cops are in *ex situ* collections – situated in, or often owned by – developed countries. There have been international exchanges and access to these materials for research, breeding and production. Individual cultivars are also accessed. There are over 6 million crop accessions held worldwide in some 1400 gene banks. As an example

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[33] Joshua Sarnoff and Carlos Correa, *Analysis of Options for Implementing Disclosure of Origin Requirements in Intellectual Property Applications*, UNCTAD, 2006, p. iv.

[34] At p. ix.

[35] At p. xi.

[36] At p. xii.

[37] It came into effect on June 2004.

[38] Not included are some crops of great value to sustainable agriculture and food security such as: soya bean, groundnut, many fruits and vegetables and tropical forages. Others that are not so wide spread include: African leafy vegetables which are potentially important as they provide nutritional well being of the populace of many developing countries and regions.

[39] Wheat came from Europe to the Americas over 500 years ago, finger millet was domesticated in Africa 4000 years ago and introduced to South Asia some 4000 years ago, maize was introduced to Europe from America on Columbus' return and then taken to Africa and managed and further developed there for more than 500 years, barley was introduced to Ethiopia more than 2000 years ago: IPGRI and IRRI, *Developing Access and Benefit-sharing Regimes: Plant Genetic Resources for Food and Agriculture*, Feb 2005, pp. 1-2.

researchers on ground nut - originally from collections in Uganda and Kenya – would most likely collect them from the ICRISAT centre in India. This centre obtained 67% of its accessions from non Kenyan/Ugandan sources.[40] So researchers often obtain germplasms from outside the country of diversity of the crop. Figures from IPGRI and IRRI's publications show that nearly all countries are net recipients of plant genetic resources. Countries have also benefited by multiplying between 2 and 20 times as many varieties as they have contributed to the accessions.[41] Also on average each variety of individual crops was a mixture of 7 land races from 4 or 5 different countries. In other words countries were dependent on foreign progenitors for their breeding programmes; for rice – up to 83%.

For this reason it is very difficult, if not impossible, to calculate the incremental contribution for each ancestors to the development of the improved varieties, advanced lines and landraces in existence. Even more complex is the difficulty in assessing the qualitative contributions of each parent parents to their progeny.[42]

Additionally, crop research is also done across institutions using a wide range of resources. Accessing these could entail a large number of material transfer agreements. IPGRI/IRRI's publication gives an example. IRRI's over 80,000 accessions are from 11 countries. 110 agreements would have to be negotiated to gain access. For all countries to get access to all of the material would require 12, 210 agreements. This would result in high transaction costs and much time.

This underlines the need for a multilateral system for access and benefit sharing.

Access under the treaty

Contracting Parties agree to give access to the crops listed in Annex 1 when these are in the public domain and under the management and control of the Parties.[43] Access should be for free or at a minimal cost. There can be no IPR or other rights claimed that could limit the facilitated access to the genetic resource or their genetic parts or components 'in the form received by the multilateral system'.

Benefit sharing

This is structured on a multilateral basis. The access is considered as the biggest benefit. Others include: exchange of information, access to and transfer of technology, capacity building, and sharing of monetary benefits from commercialisation. Those who commercialise products and incorporate that material will pay a share of the benefits arising from the commercialization into financial

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[40] Preceding note, at p. 4, footnote 8.

[41] Preceding note, at p. 2.

[42] See however the UNDP report cited earlier and the figures provided by the Rural Advancement Foundation International (RAFI).

[43] This includes Annex 1 materials held in the *ex situ* collections of the Future Harvest Centres. The treaty states that the Centres' non-Annex 1 materials will be made under substantially the same conditions.

mechanism set up under the treaty. The payment is mandatory where restrictions are placed on the availability of the product to others for further research and breeding. Otherwise it is voluntary. These funds will be used to support conservation and crop improvement, especially in developing countries and those in transition. This is the mechanism devised to share the monetary benefits with the farmers - providers of TK – in developing countries.

The terms and conditions are standard. There will be no bilateral agreements. This saves time and transaction costs.

Farmers' Rights

The Treaty recognizes the need to protect knowledge and innovations in farming under *sui generis* national Plant Variety Protection laws. These rights can be incorporated in such a law as long as it otherwise provides 'effective' protection to plant breeders.

CONCLUSION

There are large number of international fora now addressing issues in relation to genetic resources and TK. What should the synergies be between these organizations? Who should take ownership of these processes? Or, at least, be the lead organization? Where would the enforcement be most effective? These issues have yet to be addressed in a holistic manner. The horizontal cooperation is foreshadowed by the FAO's work undertaken in harmony with the CBD. As well, paragraph 19 of the DOHA WTO Ministerial implies the need to ensure the compatibility of the WTO and the CBD.[44] These several initiatives reflect the seriousness with which developing countries are pursuing the creation of a binding international agreement for the protection of TK against misappropriation. Although it is difficult to predict the precise outcome, or the time frame for its realization, what appears certain is that the journey towards that goal has commenced in earnest.

PART 7: NATIONAL EFFORTS

TRIPS provisions: Defensive basis for safeguarding

[44] Paragraph 19 of the Declaration '.. instructs the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this Declaration, to examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant developments raised by Members pursuant to Article 71.1'.

Many developing countries have introduced, or are in the process of introducing, national laws and policies for the protection of TK associated with genetic resources. Such efforts must necessarily keep in mind the overarching provisions of the obligations under TRIPS.

TRIPS is silent on genetic resources, TK, folklore and biodiversity. There are however provisions that can be interpreted as providing a defensive basis for preventing the misappropriation of genetic resources and TK.
One is Article 7 which provides:

The protection and enforcement of IPRs should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to the balance of rights and obligations.

The other is Article 27.2 which allows for the exclusion of patents on the ground of public order or morality, including prejudice to the environment. any unfair abuse or exploitation of genetic resources may thus be prevented.

Article 67 can also be invoked to require assistance from developed countries to prevent abuse of IPRs.

These Articles do not confer rights on genetic resources associated with TK, but they could be read as allowing for remedial or preventive measures against abuse.[45]

The implications of the absence of any specific provisions in TRIPS on TK means that members are free to amend their IPR laws to protect TK; or introduce *sui generis* laws to protect TK. The laws they enact will be to implement the CBD, in particular Article 8(j) – so long as it does not conflict with TRIPS.

Sufficient flexibilities in TRIPS

There are also sufficient flexibilities in TRIPS that developing countries can rely upon in formulating laws and policies in relation to TK that are compatible with their stage of development and needs and cultural values. The issue of the protection of TK must be preceded by careful analysis – not only of the rights holders, but the possible implications of protection for public health, food security and other public interests.[46]

The flexibilities under TRIPS that provide room for drafting laws and policies protective of TK and genetic resources stems from the definition of invention, the requirements of

[45] Weerawit Weeraworawit, 'International Legal Protection of Genetic Resources, TK and Folklore: challenges for the IP system', in *Trading in Knowledge,* Bellman, Dutfiled and Melendez-Ortiz (eds), Earthscan, 2003, at p. 161.
[46] Carlos Correa, 'Formulating Effective Pro-development National Intellectual Property Policies', in *Trading in Knowledge,* Bellman, Dutfiled and Melendez-Ortiz (eds), Earthscan, 2003, at p. 216.

protection and the possible exceptions to patentability.[47] The options available to developing countries in this regard can be summarized as follows:

1. As the term 'invention' is not defined in TRIPS and since there is no accepted universal concept of the term, developing countries can adopt a definition that excludes materials pre-existing in nature. The decision to do so can be based on principle or on technical and economic considerations

This is the position adopted by

Decision 344 of the Andean Group, article 6.b – substances that exist in nature and their replication are not inventions;

Argentine Patent law, article 6.g – excludes from the concept of invention 'any kind of living material or substance already existing in nature;

Brazilian Patent law, article 10.IX – no invention can be claimed with respect to 'the whole or part of natural living being and any natural biological processes'.

2. TRIPS obliges members to protect products and processes but not *uses* of a known product for pharmaceutical purposes. Such an invention relating to use of a product may be considered un-patentable because it consists of the discovery of an existing property rather than a new development, or because it falls under the exclusion from patentability of therapeutical methods – allowed by TRIPS and most national laws. It is suggested that the non-patentability of uses of an existing substance may avoid some cases of biopiracy – in which a substance found in nature is patented on the basis of the identification of a certain therapeutic use.[48]

3. The novelty requirement can be deemed lost when an invention is divulged anywhere – inside or outside the country – including by non-written means such as public use and sale. The US only recognizes does not recognize non-written means. Only publications made abroad destroy the novelty. This has permitted the US applicants to claim as novel inventions based on materials that are developed and used by indigenous and local communities and that constitutes their TK. Examples are the patents filed in respect of the neem, tumeric, basmati rice lines.

4. Providing for the exclusions from patentability of inventions that are considered to be against order public and morality. These terms are fairly fluid and it is for countries to to define the basis upon which exclusions will be allowed. Implementing the exclusion relating to order public would rest upon one's notion of what is needed to protect public values. The concept extends to the protection of human. Animal or plant life or health and may be applied to inventions that may lead to 'serious prejudice to the environment': article 27.2. The concept of morality is also based on the conception and values of a

[47] Carlos Correa, *IPRS, the WTO and Developing Countries: The TRIPS Agreement and Policy Options*, TWN, 2000, at p. 51 on – on which this part is largely based.
[48] Previous footnote, at p. 56.

society. So long as it is reasonably based on these values, it would appear to be consistent with TRIPS.

5. Article 27.3(b) requires a form of protection for plant varieties. It could be new and sui generic. National laws can require such conditions as the obligation to declare the origin of materials used and to give evidence of the country of origin/ source and the indigenous and local community whose TK is involved. It could also provide for the need for fair and equitable benefit sharing with these countries and communities.[49]

It was earlier noted that COP 8 also dealt with national measures that countries can take to support compliance with the prior informed consent (pic) and mutually agreed terms (mat) provisions of Article 15 of the CBD. The decision urges parties and others to continue taking such measures as will support compliance with pic and mat –where there is utilization of genetic resources or associated traditional knowledge – in accordance with Article 15 of the CBD and national legislation.

6. If the patentability of plants and animals is allowed, national laws may also incorporate specific provisions to limit the extent of the exclusive rights, especially relating to the multiplication of the protected materials. So patent owners, for example, should not be able to prevent the replanting of patented seeds or the exploitation of the progeny of patented animals.[50]

The EC Directive on the Legal Protection of Biotechnological Inventions allows the replanting of patented seeds without remuneration in the case of small farmers.[51]

For patents relating to breeding stock or other reproductive material, the farmer is entitled to use the protected livestock for an agricultural purpose but cannot sell the material 'within the framework or for the purpose of a commercial reproduction activity'.[52]

Other measures taken at national level

Law on farmers' rights

Some developing countries have modelled IPR laws to respond to their social and economic conditions. The Indian Protection of Plant Varieties and Framers' Rights Act 2001 is an example. It was enacted to fulfill the sui generis option in article 27.3(b) of TRIPS. There are comprehensive provisions relating to the rights of farmers – to save harvested seed of protected varieties and also to sell it as long as it is not under the protected brand name. There is a fund that must be paid into whenever breeders use farmers' varieties. The law also requires full disclosure of the source and origin of

[49] South Africa has amended its Patent legislation to effect the disclosure requirement thereby combining the CBD requirements with traditional knowledge protection – along the lines of the proposals on article 29bis of TRIPS at the WTO.

[50] Previous footnote, at p. 89.

[51] Directive No. 98/44/EC, 6 July 1998, article 11.1. There is a similar provision in the Malaysian Plant Variety Protection Act.

[52] Directive No 98/44/EC, article 11.2.

varieties and complete passport data from breeders – with heavy penalties for non-disclosure.

Documenting TK

This is being documented and published so that the innovation is in the public domain and cannot be misappropriated.

TK Digital Library

For much the same reason, the Government of India is developing a digital database of public domain TK related to medicinal plants. It is intended to make this available to patent offices in the world so that the examiners are aware of the prior art relating to a particular medicinal plant. India spent several million dollars canceling the patents in respect of tumeric and the neem and the basmati rice. Patents are granted almost routinely by examiners too over burdened with applications to carry out a proper prior art examination. There are about 3 million patents applications pending in the three main patent offices in the world – the US, the EU and Japan. The patent system is in crisis and the examiners can do little more than grant the patent. There seems to be a reversal of the burden – a patent is granted unless there is shown evidence to the contrary that it does not satisfy the criteria for patentability. There are reported to be some 2500 patents granted in error. And 500 more are added to every year!

Brazil has also recently forwarded to WIPO, the WTO and trademark offices throughout the world a 'Non-Exhaustive List of Customary Names used in Brazil associated with Biodiversity' It aims to prevent the registration of trademarks, without sufficient distinctive character, by providing trademark offices and examiners an important basis for consultation. It has had to do this as it exporters faced losses and it had to undertake costly proceedings to cancel filings or invalidate registration of generic names of its biodiversity and cultural heritage. This includes TK. This has hampered its commercialization of Brazilian commodities and products abroad.[53]

Other developing countries have also adopted data bases and registries for TK and genetic resources both individually and through regional initiatives. These include: the Traditional Chinese medicine Patent Database of China; the system of national and local registers established under Peruvian Law 278111; and the Biozula Data Base in Venezuela, which covers native medicines, ancestral technology and traditional agricultural knowledge.

NGO established Databases on TK

The American Association for the Advancement of Science Project on Traditional Ecological Knowledge together with a host of other NGOs has set up the Traditional Ecological Knowledge Prior Art Database which is an index and search engine of existing internet-based, public domain documentation concerning indigenous knowledge

[53] Press Release, Permanent Mission of Brazil in Geneva, 24 July 2006.

and plant species use. Its web site[54] states that this database brings together in a single location, various types of public domain data necessary to establish prior art. Data includes taxonomic and other species data, ethnobotanical uses, scientific and medical articles and abstracts, as well as patent applications themselves. There have been concerns expressed that this public system of TK databases or digital libraries could provide a licence to steal – as there is a neat cataloging of genetic resources and associated TK that is readily accessible to commercial researchers and scientists. This is strenuously denied by industry.[55]

CONCLUSION

Developing countries have been grappling with this problem of dealing with the misappropriation of its genetic resources and associated TK for a long time. TRIPS and the review process - more than anything else - have prompted developing countries to seek a rectification to a long festering inequity. Various options have been advanced – at both the national and international levels. These represent a plethora of possible, often creative, solutions to what is now acknowledged as a complex problem.

[54] http://ip.aaas.org/tekindex.nsf

[55] 'Comments of the American Bioindustry Alliance on WIPO Paper WIPO/GRTK/IC/9/5, 'The Protection of TK: Revised Objectives and Principles', July 31 2006. See further: footnote 29.

TK & IP: OPTIONS FOR DEVELOPING COUNTRIES

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INTRODUCTION

- DEFINING TK
  - MANNER OF PRODUCING KNOWLEDGE BASED ON TRADITIONS OF COMM
- EXISTING SYSTEMS OF KNOWLEDGE
- EMBEDDED IN WIDE ARRAY OF CULTURES – SUSTAINS BROAD SPECTRUM OF LIVES
- KNOWLEDGE: DYNAMIC AND CONTINUOUS

VALUE OF TK

- PRESERVES AND ENHANCES BIODIVERSITY
- FED, CLOTHED AND HEALED THE WORLD
- CBD – INTL ACKNOWLEDGMENT
  - ARTICLES: 8(j), 10 (c), 17(2), 18(4)

ECON CONTRIBUTION

- AGRICULTURAL CROPS
  - 15 MAJOR CROPS: MORE THAN US $50b in ANNUAL SALES IN US (UNDP study)
  - WHEAT & MAIZE: IM&WC: US $2 b in CROP PRODUCTION in indus. countries
  - RICE: IRRI: US $655 m p.a.
  - RICE: FROM TRAD CROP VARIETIES: US $400 M p.a. GLOBAL VALUE
  - BEANS: US $111 M from ICTA
  - ALSO: potato, chickpea, barley, livestock breeds, etc

Econ contrib – contd

- PHARMACEUTICALS
  - THREE-FOURTHS OF PLANTS THAT PROVIDE active ingred for drugs – from knowledge of indig peoples
  - 120 active compounds isolated from higher plants and used in medicine – 75% postive coreln with trad use of plant from which derived
  - 2/3 of plant species from Dg Cs. At least 35,000 have med value

Econ value - contd

- annual value of of Dg C germ plasm to pharma indus US $47 b as at 2000 (UNDP Study
- US $ 32 b sales of pharma globally based on Trad Medicines BUT Dg C exports of same US $ 551 m. Shortfall

RAFI

- US NCI 1986-1992 23,000 plant samples of 7,000 species collected: almost all from Dg C

Econ contd

- Soil bacteria
  - Being collected from Dg C
  - Several leading MNCs involved: Merck, Pfizer, Bristol Myers etc
  - Eg. 1990 Florida U – patented Brazilian fungus known to be lethal to fire ants - more than a billion dollars in damage to US crops.
  - Brazilian farmers were aware that something in the soil kills fire ants.

NON-ECON VALUE

- ENHANCING, INTEGRATING I AND L COMM

START OF MARGINALISATION OF TK – EMERGENCE OF OWNERSHIP RTS

- GR – COMMON HERITAGE – FREE ACCESS : see Eg. IUPGR/FAO
- STARTED: UPOV – EARLY 60s
- SOUTH – TAPPED FREELY FOR SOURCE MAT
- MODIFIED – THEN IPRS CLAIMED
- CONTRIBUTN OF I-LC IGNORED
- SPAWNED DEBATE –LED TO F'S RTS 1989
- INT GENE FUND
- INOPERATIVE – NO CONTRIBN

- 2001: BINDING AG – INTERNATIONAL TREATY ON PGRFA
- INC F'S RTS AND MLT ON ABS – see later

PATENT RTS & BIOTECH

- INEQUITY FURTHERED – EXTENSION OF PATENT RTS TO LIVING ORGs – ART 27.3(B) TRIPS/WTO
- 'PRODUCTS OF NATURE' DOCT CIRCUMVENTED : CAN CLAIM PATENTS FOR ISOLATED, PURIFIED AND IDENTIFIED GENE SEQUENCES
- CAN PREVENT DOWNSTREAM FROM MAKING/USING GENE
- IPRS RECOG PRODUCTS BASED ON, DERIVED FROM, TK

IMPAIRMENT OF TK – CONCEPTUAL BASES

- 1. DIFFERING WORLD VIEW BTW TRAD AND SCIENTIFIC
  - REALITY ONLY IF VERIFIABLE BY THEIR CRITERIA
  - SC SUPERIOR KN – ADJUDGES BEC OF INSTITUTIONAL PR OF SC IN MAINSTREAM SOCIETY

Impairment- conceptual - CONTD

- 2. USURPATION OF TK THROUGH IPRS
  - THIS BIAS UNIVERSALISED THRU TRIPS
  - DEFINITIONAL CONSTRUCTS FOR PATENTS –NO PROTECN AND RECOG OF INDIG INNOVN
    - ONLY RECOG INDIVIDUAL NOT COMM INVENTION
    - ONE-OFF INV versus INTER-GENRATIONAL;
    - FOR INDUSTRIAL APPLICN versus SOCIAL GOOD

Impairment- conceptual - CONTD

- 3.MARGINALISN OF KN SYSTEM ITSELF - LONG TERM
- ALSO INDUSTRY'S SUPERIOR POSN TO CLAIM PATENT
  - GIVEN TO THOSE WHO CAN DESCRIBE IN LANGUAGE OF CHEM/MOLEC BIOLOGY AND PATENT LAW

Impairment- conceptual - CONTD

- 4. FRAGMENTATN & ATOMISN OF CULTURAL SYSTEM
  - REDUCTIONISM: SELECT ELEMENTS
  - ENCOURAGES FRAGMENTN – ATOMISN
  - EG. WHEN SOME CALLED OWNERS OF COMM KN RES = SOCIAL DISCORD IN COMM

RESULT: BIOPIRACY

- MANY EXAMPLES- FROM TK BUT KN ITSELF DEPRECATED AS 'PRIMITIVE
  - NEEM – 34 PATENTS BY US/JAP COYS: KN 5000 YRS
  - TUMERIC, DEVIL'S CLAW, SANGRADERAGO : SOME CHALLENGED SUCCESFULLY
  - ROOT OF SERPENT-WOOD SPECIES HYPERTENSIVE DRUG
    - 1967 -90% ANTI-H DRUGS BASED ON IT

BIOPIRACY - CONTD

- KNOWLEDGE OF I-LC OF AFRICA : PATENT CLAIMS BEING MADE:
- INC various drugs, cosmetics, agri and horti products, etc from – kenya, libya, egypt, gambia, namibia, mauritius, congo, ethiopia, angola, s.africa, w africa, sierra leone, nigeria, tanzania, etc etc

(see: EI & ACB, *Out of Africa: Mysteries of ABS* , 2006)

RESTORING THE BALANCE

- 1. INTEGRATING TK INTO SC FRAMEWORKS?
  - PROBLEM: LEADS TO EXTRACTING RELEV KN – USEFUL/USELESS – eg. Weeds if of no use; yet value to indig soc
  - LEAD TO DISMEMBERMENT/fragmentn of TK = AND TO ACCELERATION OF DEMISE OF TK, REPLACEMENTG WITH SC SYSTEM

RESTORING BAL - CONTD

- 2. ACK CO-EXISTENCE OF THE 2 SYS?
  - RECOGN PLURAL & DIFFERENT
  - NO OBJECTIVE BASIS FOR SAYING ONE SUP TO OTHER
  - MERE SOCIETAL CHOICE NOT DEFENSIBLE BY OBJECT CRITERIA
  - Eg CURARE PLANT: 40 types of plants. This from w amazon. Combined – boiled 72 hrs – must avoid vapors – final product+ paste – must be injected under skin

RESTORING BAL - CONTD

- Contd
  - I-LC: say: mythical; creator gave them
  - This contr sc: pure chance/ acc/cumulative yrs of this
  - But Quirishari – plant cure jergon snake bite: becos fangs: shown by nature
  - Foremost Ethnobotanist Richard Evans now believes of 'plants communicating'!

OPTIONS OF DEVELOPING COUNTRIES: international/national efforts

- LARGELY SPURRED ON BY CBD/TK provisions
- Range: stand alone protection of cir to no iprs

- NATIONAL OPTIONS & THE WTO
  - DEFENSIVE BASIS FOR PREVENTING MISAAPROPRN – remedial prev measures ag abuse
    - A. 7: TRIPS – PROTCN ENF OF IPRS CONTRIB TO PROMO OF TECH INN ...
    - A. 27.2 TRIPS: EXCL O0N PUBLIC ORDRE & MORALITY
    - A. 67: ASSIS FR DEV CS TO PREVENT ABUSE OF IPRS

community intellectual rights

- WTO/TRIPS
  - SUFFICIENT FLEXIBILITIES
    - DEFN OF INVENTION: can excl mats pre-existing in nature. on principle or tech & econ considns: andean Dec 344, argentina, brazilian pat law
    - REQMTS OF PROTECN: must prot products & processes NOT uses of a known prod for pharma purposes. So unpat – disc of existing ppty OR exclsn fr pat fro therp methods
      ALSO: nov reqmt lost when inv divulged anywhere inc if non-written
    - POSSIBLE EXCPNS TO PATENTABILITY –PO & M – for c to decide

contd

- Contd
  - A 27.3(b0 – PV protecn sui generis. So oblign to dec origin of mats, c of origin, pic of i-lc, f&eq b-sh ags
  - If allow pat of plants and animals, can limit extent of excl rts – esp for multiplicn of prot mat: so cant prevent replanting seeds, or exploiting pat animal progeny: eg EC Directive on legal pro of biotech patents –for small farmers; also malaysian pvpa

(Is it possible + us 2 follow ops of ands etc?

OPTIONS OF DEVELOPING COUNTRIES: national

- MAINLY NATIONAL
- CIR – SOME FEATURES
- ADOPTED BY SOME ANDEAN PACT AND OAU MODEL LAW, GROWING NO. OF Cs (see Uganda National Env (Access to GR abd benefit sh) Regns, 2005;
- See also: (some still draft) - Ph, B'desh, Brazil, Costa R, India, Pakistan, Peru, S.Africa, etc.
- MALAYSIA: CONSIDERING 'Access to Biological Resources Act'. Task force since
- SARAWAK & SABAH HAS BIOD LAWS: DEAL WITH I – LC? ADEQUATE

Contd: OPTIONS OF DEVELOPING COUNTRIES: national

- Amending existing laws
- M'SIA PATENTS ACT: prov on patenting life forms, discoveries, etc

Contd – options – mainly national

- CONTRACTS- IMPLEMENTING PIC & MAT
  - Devil's Claw (Botswana): Govt regns allow trad comm to extract and NGOs to trade nationally & internationally
  - Prunus africana (Cameroon): 2 agreements signed with commercial coy for harvest & supply with comm orgns
  - Teff (Ethiopia): ABS agreement Institute of Biod Conservn & E ARC and Netherlands Coy: royalties from product developed

Contd – options – mainly national

- CONTRACTS – contd
  - Vernonia (oil seed crop): Ethiopia Inst of Biod Conservn and UK Vernique Biotech Co –royalty, non-monetary benefits etc: July 2006
- CUSTOMARY LAW & PRINCIPLES
  - Free xchange & access to Collective Bio-cultural Res (kn, innovns and practices of i-lc held collectively, linked to trad res & territories, incl genes, varieties, species, ecosys; cultural & spiritual values; and cust laws shaped w/i soci-ecol contxt of comm);
  - Recogn of coll custodianship;
  - Promo reciprocal and equal xchange;
  - Resp use & conservn –code of ethics & 'equilibrium'

How does it work?

contd – options – mainly national

- Sui generis systems to protect Coll Bio-cultural heritage (cbch)
  - In addn to nat policy & law to protect rts over CBCH, est Community-level sui gen systems
    - Aim: protect bio/material, intell/spiritual and landscape components of kn sys thru coll land tenure and res m'ment (cbch)

See further: IIED, *Protecting Community Rts over TK: Implicns of Cus Laws & Prac (based on participatory case studies of I-Ic of Peru, Panama, Kenya, India & China), 2006*

contd – options – mainly national

- Eg of Developed c law – Australia: Env Protectn & Biod Cons Am Regns 2005 – from Draft law:
  - To access bio res for commercial or potential comm purposes – applicant must get permit;
  - appl must enter into b-sh ag with access provider (ap)
  - Ap - inc owner of ind p's land & native title holder
  - Must have pic to b-sh ag
  - Ag must have reas b-sh arrangements, incl 'protectn for, recog of and valuing of any indig p's kn to be used

contd – options – mainly national

- OTHER MECHANISMS – documenting TK; TK Digital library; Databases
- Objective: protection; Benefit sharing; achieved? Achievable?

regional

- Norm setting
- ASEAN FRAMEWORK AG ON ABS, 1996
- CENTRAL AM AG DRAFT, 2001
- ANDEAN COMMUNITY DECISION 391 – COMMON REGIMES ON ACCESS TO GENETIC RESOURCES, 1996
- AFRICN MODEL LEG FOR THE PROTECN OF THE RTS OF LOC COMM, F AND BREEDERS AND FOR THE REG OF ACCESS TO BIOL RES, 2000

INTERNATIONAL LEVEL

- 1. WTO/TRIPS
- 2. WIPO
- 3. CBD
- 4. UNCTAD
- 5. ITPGRFA – FAO

Contd - Intl level

- WTO/TRIPS
  PROPOSAL DG Cs: AMEND TRIPS – A. 27.3 & 29. FOR PATENT GRANT:
  - DISC SOURCE & C OF ORIGIN OF GR & TK
  - EVID OF PIC FOR EXTRACN & USE
  - EVID OF F & EQ SH OF BENEFITS
- ALL 3 IN CERT OF ORIGIN

CONTD WTO/TRIPS

- RATIONALE:
  - IMPLEMENT TRIPS & CBD IN MUTUALLY SUPP WAY
  - SUPPL MEASURE FOR NAT REGIMES
  - INCENTIVE FOR PAT APPL TO COMPLY WITH LAW OF C OF ORIG (acc with cbd)
  - BIOP GLOBAL PHENOM – GLOBAL RESP
  - NAT REG INSUFF: OTHERS NOT HAVE SAME LAW
  - Esp Dev C: CBD/WG-ABS/4/INF/6, *ANALYSIS* … p. 28

CONTD – WTO/TRIPS

- EMERGENCE OF PROPOS: b'ground
  - 1995: IN WTO/CTE – discussions began
  - 1999: INTROD BY DG C WHEN TRIPS REVIEW of a 27.3(b)
  - 1999: SEATTLE MIN : propos to amend trips to inc TK
  - 2001: DOHA MIN: instructed TRIPS C – xmine CBD/TRIPS r/s & prot TK and f'lore
    - 'outstanding implemn issue'
    - Now outstanding issue at TNC level
  - 2005 HK MIN: WTO DG to intensify consultative process and rept to TNC & GC – which will take action end of July 2006

CONTD – WTO/TRIPS

- 3 BROAD POSITIONS:
  - 1. INHERENT CONFLICT BETWN CBD – TRIPS
  - 2. NO CONFLICT
  - 3. READ BOTH IN MUT SUPP WAY – SO NO NEED TO DO ANYTHING @ NAT/INT'L LEVEL
- DG Cs: AM TRIPS TO AVOID POTENTIAL FOR CONFLICT – SO PROPOSALS BY 9 Cs

CONTD – WTO/TRIPS

- ELABORATION OF PROPOSALS
  - FAIR & ENHANCE PAT SYST'S CREDIBILITY
  - 'FAIR & EQ' CRITERIA:
    - MAT –A. 15.7 CBD: COVERING ELEMENTS RE: CONDNS, OBLIGNS, PROC, TYPES, TIMIMG, DISTRIBN, MRCHANISM OF BENEF SHARED
    - REPORTING OBLIGN ON ISSUES re:PAT OR COMMERCLSN – ESP WHERE FUTURE BS INTENDED

CONTD

- CONTD
  - WHERE NO NATIONAL REGIME ON ABS
    - APPL MUST SO DEC
    - ALSO BSH FOR FUTURE – WITH AUTHY/ COMM WHERE GR/TK ACCESSED – IN MANNER RESPECTING LAWS ETC
  - EFFECT WHERE NO B-SH
    - APPLICN NOT PROCESSED UNTIL SUBM

CONTD

- CONTD
  - SANCTIONS & PENALTIES
    - PLUS PENALTIES – INC CRIMNL
    - TIME LIMIT TO SUBMIT – OTHERWISE DEEMED W/DRAWN. APPLICN NOT PROCESSED
    - WHERE DISC'D AFTER GRANT OF PAT
      - REVOCN OF PAT – IF INTENT FRAUDLNT
      - ADD OR ALTVE – CR/SDMINVE SANCTIONS – INCL ADEQ COMPENSN
      - FULL/PARTIAL TRANSFER OF RTS TO INVENTN
      - CR/CIVIL SANCTIONS OUTSIDE PAT SYS – INC PUNITIVE DAM

CONTD

- RESPONSES FR DEV Cs: MIXED
  - US: NO CONFLICT. CBD OBLIGNS CAN B SATISFIED BY NAT LEVEL ACTION. NO NEED TO GO TO PAT SYS OR AT WTO
    - XTRANEOUS TO PAT – so no mandate to neg
    - Supp by Korea and Japan
  - EU: AGREE PROPOSALS BASIS FOR DISC
  - Not agree - discl evid of pic & b-sh
  - Not agree - penalties

contd

- TEXT OF AMENDMTS PRESENTED
  - 6 June by 9 Dg Cs
  - For negotiations – no commitment to agree
  - 5 paras A. 29bis [A 29: condns on pat applicns]
  - Disc of inven details
  - C of source & origin 'after reas inquiry
  - Evid of compliance with leg reqmts on pic & fair and equitable b-sh
  - Required updates
  - enforcement

contd

- Dg Cs' proposals –contd
- Many more Cs supporting
  - colombia, ecuador, Venezuela, Argentina: discussing at capitals
  - some raised concerns
- EU: HAS PROPOSED AT WIPO- limits disc of c of origin to gen mat directly used in invn (WTO propos: indirectly too, and extended to TK)
  - ALSO: considers propos of Dg Cs too broad: prefers gr to biol res
  - Also: burden heavy for appl to det what is 'res' to trigegr proper discl
  - NORWAY: OWN PROPOS
  -

contd

- New Proposals: update
  - By Japan & Norway @ special session of TRIPS Council on 14 June 06
  - NORWAY'S: - same as before
    - Supports amend trips so mandatory disc of c of orig and source of gr-tk in pat applicns
    - No revocn if info incorrect/incomplete which id after grant.
    - Penalise outside pat sys
    - No disc of pic & b-sh
    - This only if nat law requires (N'way's nat law so requires)
    - At WIPO Mtg april 2006: proposed source/origin of TK also be disclosed although not linked to gr.

CONTD

- JAPAN
  - its basic posn remains the same: that the 2 treaties are mutually supportive – no need to amend TRIPS
  - it says that the work on the Dg Cs' proposals will duplicate the work of WIPO
    - See: *Patent System and GR*, Communication from Japan to Council for TRIPS, 11 June 06 IP/C/W/472

contd

- CLARIFICATIONS BY PROPOSERS – based on Brazil/India's response to Qs: 14 June 06
- 1. MUST DISC SOURCE AND C OF ORIGIN? :
  - Source can be from co that's transnational
  - CBD refers to both defns
  - Address int dimension of misappr issue. Source alone can't address this.

contd

- Contd
- 2. Why term 'biol res' used instead of gr?
  - CBD: States sov rt to expl own res. So wider
  - to cover all poss cases of biopiracy
  - Term similar to 'biol mat' – as in EU Biotech Directive (98/44)

contd

- Contd
- 3. WHAT 3 TRIGGERS MEAN IN PRACTICE?
  - COVERS SITUATIONS IN WHICH TK CONTRIBUTED TO INVN
    - 'CONCERNS': WHERE PREDOM OR SUBSTAN PART OF INVEN INCORPORATES THE GR. SAME AS IN EU DIR 98/44
    - 'DEVELOPED WITH': MAY NOT NECESSARILY INCORPORATE ANY OF GR BUT TK CRITICAL TO DEV OF INVEN
    - 'DERIVED FROM': COVERS DERIVATIVES. IN A 8.1 OF EU DIR – REFERRING TO PROPAGN/MULTIPLICN FROM ORIG MATERIAL

CONTD

- CONTD
- 4. WHO DECIDES W THERE HAS BEEN 'REAS ENQUIRY' AND WHAT IT MEANS?
  - MEANS REAS GROUNDS TO KNOW eg A 37 TRIPS – SO DUE DILIGENCE
  - FOR APP TO DET INITIALLY WHAT ENQUIRY REASONABLE TO SATISFY REQMT

CONTD

- CONTD
- 5. MEANING OF TERM 'ASSOCIATED TK?
  - RESTRICTS DISCLOSURE TO TK THAT HAS RELEV TO BIOL RES USED IN DG/CONCERNING S/M OF INVEN
  - ALSO MANY PATENT OFFICES USE THIS TERM IN DET PRIOR ART

CONTD

- CONTD
- 6. IF THE PROVIDING C HAS NO LAW FOR PIC AND ABS, THEN A DECLARATION TO THAT EFFECT BY APPL WOULD SATISFY THE REQMT

- CONTD
  - 7. 'REAS GROUNDS TO KNOW' IN PARA 5
  - MEANS: CONSIDERING THE KN OF THE APPL, THE RESOURCES AVAILABLE TO THEM AND NORMAL BUSINESS AND SCIENTIFIC PRACTICES, THEY ARE EXPECTED TO KNOW. SO APPL TO EXERCISE ORDNY DUE DIL.

CONTD

- CONTD
- 8. PARTIES CAN, POST-GRANT, SUPPLY INFO THAT IS RELEV TO FULFIL OBLIGNS
- 9. LEGAL REQMTS OF Cs will det with whom b-sh contracts to be neg

2. WIPO

- In 2004 Brazil introduced the development agenda : Proposals: among other matters, protection against misappropriation, the legal form of the protection and fair and equitable benefit-sharing and recognition of knowledge holders and PIC.
- Negs stalemate at meeting of IGC in June 2006 . ISSUE: W? to address substantive legal text before completing work on objectives and principles.
- DG Cs - Brazil, South Africa (on behalf of Africa), India etc including TK as part whole negotiation - lead to legally binding instrument.
- Japan, the United States, etc against their inclusion before the completion of talks about principles and objectives as 'foundation for further discussions'.

contd

- They and bioindustry: enforcement of ABS should be separate from the administration of patent rights; that contracts between countries made on mutually agreed terms and not an internationally binding instrument resolve problem; and that there should be developed a universal system to harmonise existing TK databases and digital libraries
- The committee will meet again on 4-12 December 2006, at the halfway point of its two-year mandate.
- The debate largely on 2 documents: WIPO/GRTKF/IC/9/4; and WIPO/GRTKF/IC/9/5.
- SEE EARLIER: POSN OF EU AND NORWAY @ WIPO

3. CBD

- IR ON ABS; BY COP7 IN KL – 2004
- ESTD WG.
- TOR incl TK as in A. 8(j), PIC, certs of origin etc, disclosure in IPR applications, protectn of i-lc over their TK subj to nat leg
- 2 mtgs
- COP 8 '06: continue neg on Granada Text.
- Schedule of work: finish by 2010
- Experts to meet on Cert of Origin in IPRs

contd

- COOPERN WITH A. 8(j) WG
- 'FULL AND EFFECTIVE PARTICIPN OF I –LC IN ALL MATTERS RE: TK WITHIN THE RULES OF PROCEDURE'.
- I-LC NOT HAPPY WITH THIS POSN

4. UNCTAD

- REPORT OT CBD ON INVITN
  - NEED FOR IN SYST OF MANDATORY DISC OF ORIGIN:
    - PREVENT MISAPRN OF GR/TK
    - PROMOTE COMPLIANCE WITH CBD ABS
    - PREVENT ABUSE OF IPR SYSTEM
  - NEED FOR NEW INTNL TREATY FOR W'WIDE IMPLEMNTN AS NOT ALL Cs HAD SUCH LAWS
  - SUGGESTED WTO AS FORUM AS WIDE M'SHIP.

5. ITPGRFA - FAO

- EST ABS FO GR – LIST OF 35 CROPS AND 29 FORAGE SPECIES
- LIST CAN BE EXPANDED BY CONSENSUS
- COMPATIBLE WITH CBS
- RATIONALE FOR MLS

CONTD

- Ps AG GIVE ACCESS TO CROPS LISTED – when in public domain and under m'ment and control of Ps. No IPR rts that will limit fac access to gr or component parts 'in the form rec'd by the mls.
- B-sh: multilat basis – those who comm products and incorporate mat pay a share to finan mechanism
- If restrictions on availability of prod to others for further research and breeding – then mandatory
- If not – voluntary
- Funds used to support cons & crop imp'ment - -esp Dg Cs
- FAO has developed standard MTAs

contd

- Recognises Farmer's rts:
- Respy for realising rts with nat govts
- Cs should as apt in acc with needs and priorities, take measures to promote
- Incl by
  - protectn of TK
  - Rt to equitably p'cipate in b-sh
  - Rt to p'cipate in decisions re: cons & sus use
- 'nothing in this … to limit any rts that F's have to save, use, exchange and sell farm-saved seed/ propagating mat, subj to nat law as appropriate'.

CONCLUSIONS

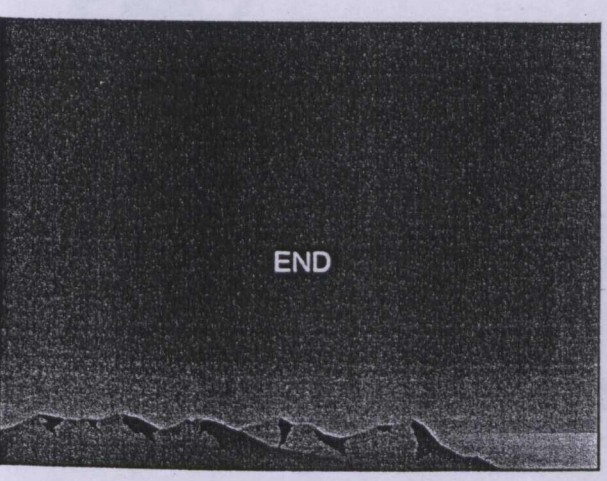
- INNOVATION, SC AND TECH, INCL IPRs DISCUSSED IN VARIOUS INT'L FOR A.
- Dg Cs ACTIVE IN ADVANCING OPTIONS
- OVERALL APPROACH IN THESE FOR A – DISPARATE
- Some horizontal coopn

contd

- CHALLENGES Dg Cs FACE IN THIS AREA:
  - MIN IPR STDS BACKED BY TRADE RETALIATION
  - LOSS AND BALANCE OF IPR POLICY & RULES- incl dangers by FTAs
  - UNDEMOCRATIC AND IDEOLOGICAL STD-SETTING PROCESSES
  - INCONSIS AND LACK OF CO-ORDN WITHIN AND AMONG Dg Cs

contd

- Dg Cs ARE CURRENTLY ONLY ONES INVESTING IN PROTECN OF PUBLIC INTEREST IN THIS AREA – INCL TK-ABS
- KEY FACTOR: Dg Cs MUST DEV BETTER COORDIN AND COHERENCE
- Then only outcome for options realisable.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